DRAFT PA Criteria

Initial Approval Date: July 10, 2019
Revised Dates: July 8, 2020; October 9, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Atopic Dermatitis (AD) Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Tacrolimus (Protopic®)
Pimecrolimus (Elidel®)
Crisaborole (Eucrisa®)
Dupilumab (Dupixent®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- For pimecrolimus, tacrolimus, and crisaborole, one of the following must be met:[1,2,8,9]
  - Patient must have had an adequate trial (at least 3 weeks)[2,3] of at least one prescription-strength topical corticosteroid or a contraindication to all agents listed in table 2.
  - Patient has atopic dermatitis on the face, neck, genitalia, skin folds, and/or axillae.[1-3,5]
- For dupilumab:
  - Must be prescribed by or in consultation with a dermatologist, allergist, or immunologist.[2,3]
  - Patient must have had an adequate trial (at least 21 days) of one of each or contraindication to all of each of the following listed in table 3: a topical calcineurin inhibitor and a phosphodiesterase-4 inhibitor.[2]
  - Patient must have had an adequate trial (at least 8 weeks) of one or contraindication (including pediatric age) to all systemic conventional agents listed in Table 4.[4]
  - Prescriber must provide the baseline of the following criteria:[2,6]
    - Eczema Area and Severity Index (EASI) score of ≥ 16.[6]
  - For all requested immunomodulating biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another immunomodulating biologic or JAK inhibitor listed in Table 5. After discontinuing the current immunomodulating biologic or JAK inhibitor, the soonest that a new immunomodulating biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits for Atopic Dermatitis (AD) Agents.[6-9]

Medication	Indication(s)	Age	Dosing Limits
Calcineurin Inhibitors			
Pimecrolimus (Elidel®)	Mild to moderate AD	≥ 2 years	Thin layer applied twice daily
Tacrolimus (Protopic®)	Moderate to severe AD	≥ 2 years	Ages 16 years and older: 0.03% or 0.1% thin layer applied twice daily Ages 2 to 15 years: 0.03% thin layer applied twice daily
Phosphodiesterase-4 Enzyme Inhibitor			

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Crisaborole (Eucrisa®)	Mild to moderate AD	≥ ~~2 years~~3 months	Thin layer applied twice daily
Interleukin-4 Receptor Antagonists			
Dupilumab (Dupixent®)	Moderate to severe AD	≥ ~~12~~6 years	Adults: 600 mg (given as two 300 mg injections) initially SC followed by 300mg every other week Ages ~~12~~6 to 17 years: 15 to < 30 kg: 600 mg (given as two 300 mg injections) initially SC followed by 300 mg every 4 weeks ~~<~~30 to < 60 kg: 400 mg (given as two 200 mg injections) initially SC followed by 200 mg every other week ≥ 60 kg: 600 mg (given as two 300 mg injections) initially SC followed by 300 mg every other week

SC: subcutaneous

LENGTH OF APPROVAL (INITIAL): 12 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must not exceed dosing limits listed in Table 1.
- For pimecrolimus, tacrolimus, and crisaborole: Prescriber must attest that the patient has received clinical benefit from continued treatment with the requested medication.
- For dupilumab:
  - Patient has documented response compared to baseline in at least one of the following measurements:
    - EASI improvement ≥ 75% compared to baseline.[6]
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 MONTHS

Table 2. List of topical corticosteroids in the treatment of atopic dermatitis.[1]

Topical Corticosteroid Agents
Alclometasone (Aclovate)
Amcinonide (Cyclocort)
Betamethasone (AlphaTrex, Diprolene, Diprolene AF)
Clobetasol (Clobex, Clobex Spray, Clodan, Cormax Scalp Application, Impoyz, Olux, Olux-E, Temovate, Temovate E)
Clocortolone (Cloderm)
Desonide (Desonate, DesOwen, LoKara, Tridesilon, Verdeso)

Desoximetasone (Topicort)
Flurandrenolide (Cordran, Nolix)
Gluticasone (Beser, Cutivate)
Halcinonide (Halog)
Halobetasol (Halac, Ultravate)
Hydrocortisone (Cortizone, Westcort)
Mometasone (Elocon)
Prednicarbate (Dermatop)
Triamcinolone (Kenalog, Trianex, Triderm)

Table 3. List of topical conventional therapy in the treatment of atopic dermatitis.[1,6]

Topical Conventional Agents	
Calcineurin Inhibitors	**Phosphodiesterase-4 Inhibitors**
Protopic® (tacrolimus 1% & 0.03%)	Eucrisa® (crisaborole)
Elidel® (pimecrolimus 1%)	

Table 4. List of systemic conventional therapy in the treatment of atopic dermatitis.[1,6]

Systemic Conventional Agents
Gengraf®, Neoral® (cyclosporine)
Azasan®, Imuran® (azathioprine)
Trexall®, Rheumatrex®, Otrexup®, Rasuvo® (methotrexate)
CellCept®, Myfortic® (mycophenolate mofetil)

Table 5. List of immunomodulating biologic agents/janus kinase inhibitors (agents not to be used concurrently).

Biologic Agents/Janus Kinase Inhibitors		
Abrilada™ (adalimumab-afzb)	Hadlima™ (adalimumab-bwwd)	Rituxan® (rituximab)
Actemra® (tocilizumab)	Humira® (adalimumab)	Rituxan Hycela™ (rituximab/hyaluronidase)
Amevive® (alefacept)	Hyrimoz™ (adalimumab-adaz)	Ruxience™ (rituximab-pvvr)
Amjevita™ (adalimumab-atto)	Ilaris® (canakinumab)	Siliq® (brodalumab)
Avsola™ (infliximab-axxq)	Ilumya™ (tildrakizumab-asmn)	Simponi® (golimumab)
Cimzia® (certolizumab)	Inflectra® (infliximab-dyyb)	Simponi Aria (golimumab)
Cinqair® (reslizumab)	Ixifi™ (infliximab-qbtx)	Skyrizi™ (Risankizumab-rzaa)
Cosentyx® (secukinumab)	Kevzara® (sarilumab)	Stelara® (ustekinumab)
Cyltezo™ (adalimumab-adbm)	Kineret® (anakinra)	Taltz® (ixekizumab)
Dupixent® (benralizumab)	Nucala® (mepolizumab)	Tremfya® (guselkumab)
Enbrel® (etanercept)	Olumiant® (baricitinib)	Truxima® (rituximab-abbs)
Entyvio® (vedolizumab)	Orencia® (abatacept)	Tysabri® (natalizumab)
Erelzi™ (etanercept-szzs)	Remicade® (infliximab)	Xeljanz® (tofacitinib)
Eticovo® (etanercept-ykro)	Renflexis® (infliximab-abda)	Xeljanz XR® (tofacitinib)
Fasenra™ (benralizumab)	Rinvoq™ (upadacitinib)	Xolair® (omalizumab)

References

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7. Eucrisa Ointment 2% (crisaborole) [package insert]. New York, NY: Pfizer Labs; ~~December 2018~~March 2020.
8. Elidel (pimecrolimus) [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals; December 2017.
9. Protopic (tacrolimus) [package insert]. Madison, NJ: LEO Pharma Inc; February 2019.

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